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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,088	07/18/2003	Robert P. Bennett	IVGN 332	1853

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EXAMINER	
HORNING, MICHELLE S	
ART UNIT	**PAPER NUMBER**
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/622,088	BENNETT ET AL.	
	Examiner	Art Unit	
	Michelle Horning	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,19,22,24-27 and 44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17, 19, 22, 24-27 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to communication filed 11/15/2007. The status of the claims is as follows: claims 17, 19, 22, 24-27 and 44 are under current examination.

Withdrawn Objections and Rejection

The following objections and rejection have been withdrawn due to amendments and persuasive arguments by Applicant:

1. Objection to the Drawings;

2. Objection to the Specification; and

3. 35 USC 103 (Anderson et al, 1982).

Claim Rejections - 35 USC § 102-NEW

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 17 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5348886 ("Lee et al").

Lee et al disclose a method of producing recombinant viruses utilizing a baculovirus genomic DNA (see Abstract). The methods include steps where a first nucleic acid molecule (transfer vector) comprising baculovirus DNA having two site-specific transposon sites (i.e. site-specific recombination) and a second nucleic acid molecule (transfer vector) comprising a gene of interest by site-specific sequences, whereby each transfer vector is treated in vitro, such as in restriction digests/ligation reactions (see column 14, lines 20-35; columns 15-16; Figure 1 which depicts AcNPV and pMON14272 vectors). Also, the authors disclose a selectable drug resistance marker (see Abstract) and the pUC origin of replication (see Figure 3 and corresponding legend). Further, the resulting composite bacmid is introduced in to insect cells (see Abstract). The nucleic acid molecules are ultimately manipulated so as to prepare a recombinant virus (see Figure 1, vector designated as vMON14272). During the construction of the recombinant virus, the vector comprising the baculovirus DNA is digested with at least one restriction enzyme, such as *NcoI*/*Eco*RI (see column 14, lines 20-25). The authors describe this method as a novel method for making heterologous proteins (i.e. encode by the gene of interest) as well for rapid protein engineering of eukaryotic proteins (see whole document). Therefore, this reference anticipates the rejected claims.

Claims 17, 19, 22, 24-27 and 44 are rejected under 35 U.S.C. 102(a) as being anticipated by Loftus et al (2001).

Loftus et al disclose "the first instance of site-specific recombination being used to generate retroviral gene constructs" (see Abstract). They teach that

Replication-Competent Avian sarcoma-leukosis Virus (ASLV) long terminal repeat (LTR) with Splice acceptor (RCAS) vectors as useful tools for the introduction and expression of genes in both cell culture and animal model systems (see Introduction). In order to gain a more time efficient strategy, the authors modified the vectors to allow efficient introduction of genes while simultaneously creating epitope tag fusions (see Introduction). The authors created three RCAS vectors that allow the transfer of genes via Gateway recombinational cloning (see Figure 1 for the modified entry vectors which comprise *att*R sites). Of note, the destination vectors contain a *Pme*I restriction site and the vectors were propagated in DB3.1 cells (see Figure 1 legend). See under Results and Discussion for the following recitation regarding making recombination process: "These *att*B-linkered PCR products can then be cloned using donor vectors containing *att*P1 and *att*P2 sites using INT and IHF. Following the recombination between the *att*B1 and *att*P1 sites, and *att*B2 and *att*P2 sites, sequences for *att*L1 and *att*L2 are generated, and the resulting plasmid clone is termed an entry vector. Final transfer of the gene of interest from the entry clone (containing *att*L sites) to any of the final destination vectors can be accomplished by incubation with INT, IHF, and XIS" (see page 222). All three vectors were used to transduce mouse cells and all three constructs resulted in EGFP signaling indicating that the gene products could be expression from the modified vectors (see page 223 and Figure 3). In sum, the authors state the following: "The recombinational cloning procedure rapidly and efficiently yielded inserted cDNA clones in the correct orientation due to negative selection

(ccdB gene), positive selection (antibiotic) and sequence specific of flanking att sites" (see pages 223-4). Further, this modified vector eliminates the need to be dependent on restriction enzyme sequences within either the gene or vector. No adverse effects were observed with respect to the infectious virus to be produced or the gene to be expressed (see page 224). Thus, the limitations of the rejected claims above are met. Please note that retroviruses possess an RNA genome.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17 and 44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 17

and 18 of U.S. Patent No. 7198924. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to the recombination of two nucleic acid molecules via *att*L/*att*R recombination. Applicants have chosen to defer responding to the above rejection. Thus, this rejection is maintained.

Conclusion

NO claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michelle Horning
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